DAIDS
Bethesda, MD, USA

Appendix

Examples of Corrective Actions

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Examples of Corrective Actions

Examples of actions that may be taken in response to unanticipated problems involving risks to participants or others may include but are not limited to:

1. Implementing a protocol change to eliminate an apparent immediate hazard for participants before obtaining Institutional Review Board (IRB)/Ethics Committee (EC) approval or DAIDS concurrence.
2. Modifying the informed consent document(s) to include a description of newly recognized risk(s) and providing an information sheet about newly recognized risk(s) to previously enrolled participants.
3. Modifying the inclusion or exclusion criteria to mitigate the newly identified risks.
4. Implementing additional procedures to monitor the participant safety.
5. Suspending new participant enrollment or terminating the protocol and developing a plan to consider the well-being of currently enrolled participants.

Examples of actions that may be taken in response to serious or continuing noncompliance may include but are not limited to:

1. Informing current participants of information that may affect their willingness to continue in the research.
2. Designating a new PI who will assume responsibilities for the participants and carrying out the IRB/EC decision.(*note*: this may require Program Officer and Grants Management approval)
3. Requiring additional training or re-training for the PI and/or study team.
4. Increasing monitoring of the research by requiring the PI to submit special reports (e.g., adverse events or outcomes, quarterly progress reports, increasing frequency of continuing review) for ongoing research activities.
5. Suspending the grant.[1]

Examples of actions that may be taken in response to suspension or termination of IRB/EC approval may include but are not limited to:

[1] NIH Grant Policy Statement- Part II: Terms and Conditions of NIH Grant Award, 8.5.2 Suspension, Termination, and Withholding of Support, http://grants.nih.gov/grants/policy/nihgps_2011/nihgps_ch8.htm#_Suspension,_Termination,_and

1. Notifying currently enrolled participants that the study has been suspended or terminated, including the rationale for such action and informing participants of any follow-up procedures permitted or required by the IRB/EC.
2. Withdrawing currently enrolled participants when withdrawal will not adversely affect their rights and welfare.
3. Allowing participants to continue on study (e.g., treatment with an investigational drug) if the IRB/EC determines that it is in their best interests.
4. Requiring the PI to submit a proposed procedure for management of participants on the study and special reports (e.g., adverse events or outcomes, increasing frequency of continuing review) concerning participants or requiring additional training or re-training for PI and/or study team.
5. Appointing a senior investigator as a mentor for current and/or future research activities until desired competence is achieved.